UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY PATENT LITIGATION	**MDL NO. 1592**
IMMUNEX CORPORATION, a Washington Corporation and AMGEN INC., a Delaware Corporation,	**CIVIL ACTION NO.: 04-10740-MLW**
	C. D. Cal. No. CV 03-4349 MRP (CWx)
Plaintiffs,	**Judge Mark L. Wolf**
vs.	
THE TRUSTEES OF COLUMBIA UNIVERSITY in the City of New York, a New York Corporation,	
Defendant.	
AND RELATED COUNTERCLAIM.	

MEMORANDUM OF PLAINTIFFS AMGEN INC. AND IMMUNEX CORPORATION IN OPPOSITION TO COLUMBIA UNIVERSITY'S "EMERGENCY MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION"

Columbia failed in its recent attempt to stay proceedings and thus further postpone determination of the merits of this litigation. It now seeks to achieve the same result through an "emergency" motion. Columbia's covenant not to sue (the "Covenant"), however, contains two important limitations that reinforce Amgen's reasonable apprehension of an infringement suit based on one or more claims in the '275 patent: First, Columbia's Covenant is limited by the date September 1, 2004, and thus would leave Amgen subject to attack for on-going activities in

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which it regularly engages, including conduct actually occurring since September 1, 2004. Additionally, Columbia's Covenant expressly excludes any claims that may issue under its co-pending and related '159 patent application, but the same rationale that requires Columbia to covenant as to any claims in the '275 patent (or substantially identical claims) if they emerge from the pending reissue proceeding applies with equal force to those same claims if they emerge from the '159 application – **REDACTED** As a result, this motion should be denied.

Moreover, even if the Court found the Covenant sufficient to extinguish subject matter jurisdiction over Amgen's declaratory relief action as to the validity of claims in the '275 patent, other issues remain within the Court's subject matter jurisdiction: Amgen's claim for declaratory relief regarding contract rights remains; Amgen's request for a declaration of "exceptional case" and an award of fees remains. Finally, Columbia's suggestion that the Court remand pieces of these actions now is premature and should be denied.

BACKGROUND FACTS

By motion dated June 10, 2004, Columbia sought to stay these proceedings, in order to delay them while re-examination and reissue proceedings went forward in the Patent and Trademark Office. By Order dated August 16, 2004, this Court denied this motion for stay.

On September 1, 2004, Columbia again sought to stay these proceedings – this time by filing its Covenant and, on the next day, this "emergency" motion to dismiss. In a telephonic status conference with the Court on September 9, some of the features of Columbia's Covenant were explained and clarified, and since then the parties' communications have further clarified a number of features of the scope of the Covenant. *See* correspondence of September 10, 15 and

17, 2004, in Exhibit A hereto, which was also filed as Exhibit A to the Joint Report filed September 20, 2004.

By that exchange of correspondence, however, Columbia clarified that two important limitations remain:

1. Columbia clearly refuses to covenant as to transformation of CHO cells performed for production of new target proteins after September 1, 2004.[1] As discussed below, that means that important activity of Amgen after September 1, 2004, still presents a case or controversy.

2. Columbia clearly refuses to covenant as to claims substantially identical, or even identical, to those contained in the '275 patent, if those claims are allowed under its pending '159 patent application.[2] As discussed below, the facts of that '159 application and its relationship to the '275 patent mean that a case or controversy remains.

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[1] Columbia's clarification was explicit:

"4(a). If a scientist working at a plaintiff creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(b). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to methods of using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004.

4(c). If a scientist at one of the plaintiffs creates for the first time after September 1, 2004, a DNA construct or a cotransformed cell, such as a first cotransformation with a DNA I encoding for a particular protein, the Covenant does not extend to a protein produced using such DNA construct or cotransformed cell, unless such protein encoded by the DNA construct or cotransformed cell was on sale by such plaintiff on or before September 1, 2004."

Letter, Gindler to Counsel, Sept. 17, 2004, in Exh. A hereto.

[2] Again, Columbia's clarification was explicit:

"5(b). The Covenant does not extend to any claim in any patent that may issue in the future based on the '159 application, without exception."

Letter, Gindler to Counsel, Sept. 17, 2004, in Exh. A hereto.

ARGUMENT

I. Columbia's Covenant Does Not Deprive the Court of Jurisdiction Over Amgen's Declaratory Relief Claims.

Columbia correctly notes that in a patent case subject matter jurisdiction over a declaratory relief claim is found where there exists

> both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995) (citation omitted). But Columbia overreaches when it argues that "a covenant not to sue removes any 'reasonable apprehension' of suit." Columbia Mem. at 5. Whether a covenant removes the reasonable apprehension of suit depends on all the circumstances, including the terms of the covenant given. *See Gillette Co. v. Optiva Co.*, 2000 WL 307389 at *6 (S.D.N.Y. 2000) ("words carefully chosen will not negate the possibility of an infringement action"). The exceptions in the terms of Columbia's Covenant fail to remove, and in fact punctuate, Amgen's reasonable apprehension of suit.

A. The Covenant is insufficient to negate a case or controversy because it fails to extend to transformation for new proteins after September 1, 2004.

Columbia's Covenant does not extend to acts of transformation for new proteins after September 1, 2004. That means that current activities of Amgen are not protected by the Covenant, and a case or controversy persists under the facts of this case.

This is not a case like *SVG Lithography Systems, Inc. v. Ultratech Stepper, Inc.*, C.A. No. 01-11766-MLW (March 6, 2004), where there was **no** ongoing product in dispute being made, and mere speculation that such production **might** occur in the future. Nor is this case like *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999) or *Super Sack, supra*, where a

covenant was made as to a particular product covered by a particular product patent with no new product on the horizon. The static nature of those disputes convinced the courts that the mere possibility of litigation over "new products" not yet made or sold did not create a ripe controversy, because "'[t]he residual possibility of a future infringement suit based on . . . future acts is simply too speculative a basis for jurisdiction over . . . [a] counterclaim for declaratory judgments of invalidity.'" *Amana*, at 172 F.3d 855-56 (quoting *Super Sack* at 57 F.3d 1060). By contrast, in the pharmaceutical industry, the practice of methods and the fluid creation of "new products" are regular events, not mooted by Columbia's Covenant which extends only to September 1, 2004.

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These activities continue at Amgen every day. *See* details regarding this in the Confidential Declaration of Sylvia Hu, Ph.D., submitted for filing under seal herewith.

B. <u>The Covenant is also insufficient to negate a case or controversy because it fails to extend to each claim substantially identical, or even identical, to a claim in the '275 patent if such claim issues under the '159 patent application</u>.

Under the authorities on which Columbia relies, it was necessary for Columbia to covenant that it will never file a patent infringement suit based on the ***claims*** of the '275 patent as they read when issued. *See, e.g., Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991). *Spectronics* appears to be the only decision on these questions where, as here, a reissue application was actually pending. In *Spectronics*, the patentee stated that Spectronics had no liability "for infringement of claims 1-18" and promised not to sue "for infringement of

claims 1-18." *Spectronics*, supra, at 940 F.2d 632. This form of concession would cover ***each*** claim as currently written and (because it conceded liability) each claim substantially identical.

Columbia has now conceded that "the legal consequence" of such a covenant is that it also extends to any identical or substantially identical claim that may emerge from the reissue proceedings regarding the '275 patent. Letter, Gindler to Counsel, Sept. 17, 2004, in Exh. A hereto, at paragraph 5(a).[3] This admitted legal consequence follows even though one cannot know with certainty what will emerge from the '275 reissue proceeding, because the prospect of a case or controversy as to the particular claim language already asserted (or substantially identical claim language) is sufficiently concrete even though the outcome of the '275 reissue proceeding is unknown.

The same rationale that requires the patentee to extend the covenant to identical and substantially identical claims in a pending reissue application also should require the patentee to extend the covenant to such claims in a co-pending patent application. While there was no co-pending application in *Spectronics*, there is one here – the '159 application –

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. As Columbia has argued to the Court, "there must be overlapping issues" between the '275 patent and the '159 application.[4] **REDACTED**

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[3] "The letter dated September 10, 2004 ("September 10 Letter) was not a modification of the Covenant in stating that 'The Covenant applies to any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads.' The quoted statement is simply the legal consequence of the Covenant, as explained in *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991), and *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999)."

[4] "THE COURT: Is it [the decision on the '159 application] affected by the reexamination and reissuance regarding the '275?

"MR. GINDLER: Nothing we've been told by the Patent Office says that. It wouldn't surprise me if it were, because there must be overlapping issues, but I just don't know if they're going to look at them together or not." June 24, 2004 Hearing Transcript, at 77:16-22, copy attached as Exhibit B.

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Columbia refuses, however, to extend this same protection to the same or substantially identical claims if they emerge under its '159 patent application. Its refusal would enable Columbia to sue Amgen in the future merely for continuing conduct that predated the Covenant, on the theory that such conduct infringed a claim of the '275 patent that emerges under guise of the '159 application. This would bring the same claims to bear through the back door that cannot come through the front door, and thus avoid the protection that naturally flowed from the covenants in the cases on which Columbia relies.

Columbia appears to base its exclusion of the '159 application on the general principle that declaratory relief is not usually available with respect to patent applications where no claim has yet issued, because there is no claim to be declared valid or infringed. *See, e.g., GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 482 (Fed. Cir. 1996). However, a much more concrete issue is presented here. Columbia is refusing to covenant with regard to the same, specific claims in the '275 patent or substantially identical claims – a known quantity – if they are issued under the '159 application.

This is not a speculative possibility.

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Thus, it is likely that Columbia may take one of the '275 claims and urge its issuance **either** as a reissuance of the '275 patent **or** as part of the '159 application.[7] Yet Columbia, while now conceding that the Covenant must cover reissuance of such claims under the patent number '275, still refuses to have the Covenant cover any such claims that may issue under the '159 application.

In a situation of this nature, courts are not required to ignore the history of the patentee's behavior in assessing the reasonableness of the accused party's apprehension. *AIR-Vend, Inc. v. Thorne Industries, Inc.*, 625 F. Supp. 1123, 1127 (D. Minn. 1985), *aff'd*, 831 F.2d 306 (Fed. Cir. 1987). Columbia's conduct – brandishing its '275 patent REDACTED

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and now refusing to include in the Covenant any claims whatever that may emerge from the '159 patent application – distinguishes this case. Unlike the situation where a plaintiff simply fears that a pertinent patent may someday issue from a pending patent application, Columbia's conduct here gives rise to a reasonable apprehension that Columbia will make the same attack based on any identical or substantial claims that it obtains under the '159 patent application. *See, e.g., Kos Pharmaceuticals, Inc. v. Barr Laboratories*, 242 F. Supp. 2d 311, 316 (S.D.N.Y. 2003) ("Based on the vigor that Kos has displayed in enforcing against Barr its rights under the Listed Patents, it is objectively reasonable to presume that Kos might pursue another course of litigation against Barr with regard to the substantially similar Unlisted Patents"). Contrary to Columbia's argument, the rationale of *Spectronics*, requiring the covenant to apply to the same or substantially identical claims, applies with equal force to claims in the reissue application and in the co-pending application.

II. In Any Event, the Issue of "Exceptional Case" Remedies is Still Within the Jurisdiction of the Court, as is Declaratory Relief.

Courts have held that they retain subject matter jurisdiction over claims for attorneys fees in patent cases based on "exceptional case" status even where declaratory relief claims have been dismissed for lack of jurisdiction. *See Knauf Fiber Glass v. Certainteed Corp.*, 2004 WL 771257 at *1-2 (S.D.Ind. 2004) (holding that district court retains jurisdiction over claims for attorney's fees under 35 U.S.C. § 285 despite dismissal of declaratory relief claims following patentee's covenant not to sue); *Ericsson, Inc. v. Harris Corp.*, 2001 WL 257838 at *6-7 (N.D.Tex. 2001) (court retaining jurisdiction to consider claim for attorney fees under § 285 after dismissing declaratory judgment action insofar as it sought adjudication of invalidity, unenforceability or non-infringement); *see also H.R. Technologies, Inc. v. Astechnologies, Inc.*,

275 F.3d 1378, 1386 (Fed. Cir. 2002) (holding that counterclaim for attorney's fees under 35 U.S.C. § 285 is unaffected by dismissal of infringement claims due to lack of standing).

Thus, even if the Court were to conclude that it lacked jurisdiction over the plaintiffs' claims for declaratory relief, it would nonetheless retain subject matter jurisdiction over their claims for attorney's fees based on the "exceptional case" issue.

In this Court's Memorandum and Order in *SVG Lithography Systems, Inc. v. Ultratech Stepper, Inc.*, *supra*, the Court noted that the decision in *Hudson v. Principi*, 260 F.3d 1357 (Fed. Cir. 2001) stated that "there cannot be an award of attorneys' fees unless the court has jurisdiction of the action." However, the *Hudson* court denied relief under the Equal Access to Justice Act ("EAJA"), which expressly conditions the ability to award fees on the underlying jurisdiction of the court: the court "shall award to a prevailing party other than the United States fees and other expenses ... brought by or against the United States *in any court having jurisdiction* of that action...." *Id.* at 260 F.3d 1363 (emphasis added). Section 285 of the patent statute is not so conditioned, but states that "[t]he court in exceptional cases, may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285.

And although the circumstances of the *SVG* case did not so warrant, the Court also recognized that jurisdiction might exist for rulings under section 285 "where the party against whom fees are sought destroyed subject matter jurisdiction that once existed" – exactly what Columbia argues here. *See, e.g., Imagineering, Inc. v. Van Klassens, Inc.*, 53 F.3d 1260, 1266-67 (Fed. Cir. 1995) (after plaintiff conceded its patent was invalid, court still considered question of attorney fees under section 285, though denying them on the merits). This Court also recognized that, apart from section 285, there may still be jurisdiction to consider attorneys' fees

pursuant to Rule 11 or the inherent power of the court. As noted in the case cited by this Court, *Schlaifer Nance & Co., Inc. v. Estate of Warhol*, 194 F.3d 323, 333 (2d Cir. 1999):

> The District Court clearly had jurisdiction to impose sanctions irrespective of the status of the underlying case because the imposition of sanctions is an issue collateral to and independent from the underlying case. *See Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 395-96, 110 S.Ct. 2447, 110 L.Ed.2d 359 (1990) ("a federal court may consider collateral issues after an action is no longer pending," including motions for costs, attorney's fees, contempt sanctions and Rule 11 sanctions because they are "not a judgment on the merits of an action") . . . .

Columbia erroneously states that only certain of the other plaintiffs (Biogen, Wyeth et al.) raise claims for a declaration of "exceptional case." That is not accurate. Amgen's claim for such a declaration is contained in paragraph 97 of its Eighth Claim for Relief. Columbia also ignores the fact that Amgen's First Claim for Relief is broader than merely addressing the question whether royalties are due to Columbia by reason of the pendency of patent applications (a claim Columbia has since abandoned). Amgen's First Claim for Relief seeks a declaration whether any royalties are owed after August 2000 under the parties' contract, whether by reason of pending patent applications or otherwise.

III. The Court Should Not Remand at this Time.

In determining whether remand of transferred actions is appropriate now, this Court has wide discretion. Unless this Court suggests remand, "any party advocating remand before the Panel bears a strong burden of persuasion" because this Court "is in the best position to discern, and recommend to [the Judicial Panel on Multidistrict Litigation] whether the claims . . . are ripe for remand." *In re Air Crash Disaster in Ionian Sea*, 438 F. Supp. 932, 943 (J.P.M.L. 1977).

In this case, there appear to be significant common questions, including Columbia's repressive practices that excuse contractual performance by plaintiffs, claims for attorneys' fees, Columbia's demands of royalty from Amgen under the expired Axel patents (raising questions of

the scope of those patents and the meaning of their terms), and issues regarding the purported termination of licenses. In *In re Midwest Milk Monopolization Litigation*, 386 F. Supp. 1401 (J.P.M.L. 1975), the Panel declined to separate and remand supposedly "simple contract claims" regarding milk sales from the antitrust claims present in the case, because the Panel was "not persuaded [that] the [defendant's] defense to [plaintiff's] contract claims [did] not involve questions of fact common to its antitrust counterclaim." *Id.* at 1403. Similarly here, the question of the history of the '275 patent, and issues concerning the meaning of terms overlapping that patent and the expired Axel patents, are not only overlapping among the parties but continue to be present on the plaintiffs' various claims that are not extinguished by Columbia's Covenant.

In addition, it is appropriate to decline remand where there is a significant possibility of further resolution or settlement of the issues in the case by the transferee court which has become familiar with the parties and issues. As the court noted in *In re Patenaude*, 210 F.3d 135, 145 (3rd Cir. 2000):

> In the instant case, where the possibility exists that even individual settlement negotiations will be more efficient if facilitated by a judge who is intimately familiar with the general issues and many of the parties, and where in fact the record reflects that settlements are successfully being negotiated, one cannot say that the Panel abused its discretion in refusing to remand.

CONCLUSION

For the above reasons, Amgen requests that the Court deny Columbia's "Emergency Motion to Dismiss for Lack of Subject Matter Jurisdiction."

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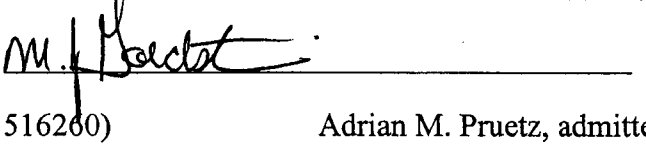
CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the document to be served by mail on September 22, 2004, upon the following parties at the following addresses. All of the plaintiffs' counsel were served redacted versions of the documents. Columbia's counsel was served unredacted versions of the documents.



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